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EXAMINER

STEELE, AMBER D

ART UNIT

PAPER NUMBER

1639

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,695	<b>Applicant(s)</b> FRENDUEUS, BJORN	
	<b>Examiner</b> AMBER D. STEELE	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009 and 21 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31 and 34-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31 and 34-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/3/05</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. The preliminary amendment received on March 3, 2005 canceled claims 1-30 and added new claims 31-59.

The amendment received on December 21, 2009 amended claims 31, 34-36, 38-40, 42-47, 50, and 52-54.

Claims 31 and 34-54 are currently pending and under consideration.

### ***Election/Restrictions***

2. Applicant elected, with traverse, Group I (wet bench method; claims 31, 34-38, and 40-54) in the reply filed on August 26, 20008.

### ***Priority***

3. The present application claims status as a National Stage application (i.e. 371) of PCT/EP03/09991 filed September 3, 2003. The present application also claims foreign priority to UK 0220506.0 filed September 4, 2002.

### ***Information Disclosure Statement***

4. The information disclosure statement filed March 3, 2005 is being considered by the examiner in view of the references submitted on February 18, 2009.

### **Withdrawn Objection**

5. The objection to claims 34-36, 38-40, 43, 47, 50, and 52-54 regarding the dependency is withdrawn in view of the claim amendments received on December 21, 2009.

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**New Objection**

***Claim Objections***

6. Claim 39 is objected to because of the following informalities: “claims” should be “claim”. Appropriate correction is required.

**Withdrawn Rejections**

7. The rejection of claims 31 and 34-54 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention regarding first subtractor and second target is withdrawn in view of the claim amendments received on December 21, 2009.

8. The rejection of claims 31 and 34-54 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention regarding the separation means.

**New Rejections Necessitated by Amendment**

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 31 and 34-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. This is a **new matter** rejection. Applicant should specifically point out the support for any amendments made to the disclosure. Applicant has neglected to point out support for the amendments received on December 21, 2009.

### **Maintained Rejections**

#### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 31, 34-35, and 38-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Lonberg et al. U.S. Patent 7,135,287 (371 date of April 1, 2002; effective filing date of October 2, 1999).

For present claims 31, 34-35, and 38-39, Lonberg et al. teach display selection methods to screen libraries of human immunoglobulins comprising: (i) providing a library of antibodies,

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ii-iii) providing ligands including ligands for negative selection, prescreening, and/or targets including antigens, (iv-vi) utilizing the universal law of mass action to determine the amount of ligands, (vii) separating antibodies from ligands, and (viii-ix) repeating the selection and separation steps (please refer to the entire specification particularly the abstract; columns 1-4, 7, 10, 15-28, and 30; Examples 13, 20-21, 26, and 35). Regarding the equations in claims 31 and 38-39, since applicants elected a wet bench method, these steps equate to a mental process (i.e. mathematical manipulation). See MPEP § 2111 and *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969). Also refer to [scienceworld.wolfram.com](http://scienceworld.wolfram.com) regarding the equation for the Law of Mass Action (3 pages).

For present claims 40-42 and 45-46, Lonberg et al. teach cell membranes and cell vesicle screening (please refer to the entire specification particularly Example 26).

For present claims 43-44 and 47-49, Lonberg et al. teach different densities, density centrifugation, and sucrose gradients (please refer to the entire specification particularly columns 24, 26-27, 30; Examples 13).

For present claims 50-51, Lonberg et al. teach phage display (please refer to the entire specification particularly columns 18-21; Examples 5-8, 11, 13).

For present claims 52-53, Lonberg et al. teach antigens and antibodies (please refer to the entire specification particularly columns 4, 20-28; Examples 13, 15-21, 23-25, 34-35).

For present claim 54, Lonberg et al. teach stimulating cells to produce antigens or antibodies (please refer to the entire specification particularly columns 15-16; Examples 13, 15-16, 23-25, 34-35).

Therefore, the teachings of Lonberg et al. anticipate the presently claimed method.

***Arguments and Response***

13. Applicants' arguments directed to the rejection under 35 USC 102 (e) as being anticipated by Lonberg et al. for claims 31, 34-35, and 38-54 were considered but are not persuasive for the following reasons.

Applicants contend that Lonberg et al. does not apply the law of mass action. In addition, applicants state that patents covering the same subject matter, which incorporate the same equations, have been granted in the UK and Europe.

Applicants' arguments are not convincing since the teachings of Lonberg et al. anticipate the method of the instant claims. Lonberg et al. teach utilizing the law of mass action (please refer to the entire specification particularly column 26). Also refer to scienceworld.wolfram.com regarding the equation for the Law of Mass Action (3 pages).

It is unclear how UK and European patent prosecution alters the rules and regulations for patent prosecution in the US. In addition, if applicants are aware of patents "covering the same subject matter, which incorporate the same equations", they are respectfully reminded of the duty to disclose information. See CRF § 1.56.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 31 and 34-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lonberg et al. U.S. Patent 7,135,287 (371 date of April 1, 2002; effective filing date of October

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2, 1999) and Marks et al. U.S. Patent 6,794,128 (filed February 12, 1999; effective filing date of April 24, 1998).

For present claims 31, 34-35, and 38-39, Lonberg et al. teach display selection methods to screen libraries of human immunoglobulins comprising: (i) providing a library of antibodies, ii-iii) providing ligands including ligands for negative selection, prescreening, and/or targets including antigens, (iv-vi) utilizing the universal law of mass action to determine the amount of ligands, (vii) separating antibodies from ligands, and (viii-ix) repeating the selection and separation steps (please refer to the entire specification particularly the abstract; columns 1-4, 7, 10, 15-28, and 30; Examples 13, 20-21, 26, and 35). Regarding the equations in claims 31 and 38-39, since applicants elected a wet bench method, these steps equate to a mental process (i.e. mathematical manipulation). See MPEP § 2111 and *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969). Also refer to [scienceworld.wolfram.com](http://scienceworld.wolfram.com) regarding the equation for the Law of Mass Action (3 pages).

For present claims 40-42 and 45-46, Lonberg et al. teach cell membranes and cell vesicle screening (please refer to the entire specification particularly Example 26).

For present claims 43-44 and 47-49, Lonberg et al. teach different densities, density centrifugation, and sucrose gradients (please refer to the entire specification particularly columns 24, 26-27, 30; Examples 13).

For present claims 50-51, Lonberg et al. teach phage display (please refer to the entire specification particularly columns 18-21; Examples 5-8, 11, 13).

For present claims 52-53, Lonberg et al. teach antigens and antibodies (please refer to the entire specification particularly columns 4, 20-28; Examples 13, 15-21, 23-25, 34-35).



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For present claim 54, Lonberg et al. teach stimulating cells to produce antigens or antibodies (please refer to the entire specification particularly columns 15-16; Examples 13, 15-16, 23-25, 34-35).

However, Lonberg et al. does not specifically teach utilizing an excess of one ligand over another ligand.

For present claims 36-37, Marks et al. teach methods of selecting phage displayed antibodies comprising contacting target cells with a phage display antibody library and also contacting the phage display antibody library with subtractive cells wherein the subtractive cells are in at least a 2 fold excess of the target cells and including 100 fold or 1000 fold excess (please refer to the entire specification particularly the abstract; columns 2-3, 12-13, 15, 18-19, 39; claims 1-42).

The claims would have been obvious because a particular known technique (i.e. subtractive screening of an antibody phage displayed library with 100 fold excess of subtractor to target as taught by Marks et al.) was recognized as part of the ordinary capabilities of one skilled in the art. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

### ***Arguments and Response***

16. Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Lonberg et al. and Marks et al. for claims 31 and 34-54 were considered but are not persuasive for the following reasons.

Applicants contend that Lonberg et al. does not apply the law of mass action.

Applicants' arguments are not convincing since the teachings of Lonberg et al. and Marks et al. render the method of the instant claims *prima facie* obvious. Lonberg et al. teach utilizing

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the law of mass action (please refer to the entire specification particularly column 26). Also refer to scienceworld.wolfram.com regarding the equation for the Law of Mass Action (3 pages).

### ***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/  
Primary Examiner, Art Unit 1639